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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,638	02/10/2001	Stephen J. Williams	0225-0032.30	9345

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EXAMINER

BROWN, JENNINE M

ART UNIT	PAPER NUMBER
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1755

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/780,638

Applicant(s)

WILLIAMS ET AL.

Examin r

Jennine M. Brown

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-- Th MAILING DATE of this communication appears on th cover sheet with th correspond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 13-17 rejected under 35 U.S.C. 102(b) as being anticipated by Ramsey, et al. (US 5858187).

Ramsey, et al. teach a method and apparatus for injection of a fluorescently tagged liquid sample into a microfluidic device having a channel network as shown in Figure 1 where channels (21, 23) are axially spaced and intersect (26) and second axially spaced channels (21, 25) with another intersection (28). Sample injection is done through sample stacking to focus the sample. Figure 4 A illustrates movement of sample from wells into separation channels and waste by controlling the voltage to upstream and downstream channel portions and side channels. A sharpening of the boundaries of the sample volume at the channel intersection is illustrated in Figure 2. Axial and proximal spacings of said channels are illustrated by Figures 1 and 3, respectively. Electrophoretic separation inherently occurs in a sample with different electrophoretic mobilities, which are based on charge and size of the molecules. Some of these molecules will move slower (trailing) and some of these molecules will move faster (leading) causing separation of the molecules. Ramsey, et al. teach a method of moving an electrolyte solution in the upstream channel successively through the first through third ports away from the electrolyte channel having the samples converge at the intersecting point and move

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downward, focusing the sample. (col. 2, l. 4-8; col. 3, l. 34-35; col. 4, l. 66 – col. 5, l. 5, 43-48; col. 7, l. 2, 33-36, 49-51; col. 9, l. 32 – col. 12, l. 43; Figures 1, 2, 4A, 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-12 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey, et al. (US 5858187) in view of Chow, et al. (US 6174675).

Ramsey, et al. teach a method and apparatus for injecting liquid sample as described above. Ramsey, et al. do not specifically teach the use of both AC and DC currents to perpendicular (axial) channels. Chow, et al. teach the use of both AC and DC currents and the use of AC and DC currents applied in a perpendicular method between at least three channels (col. 17, l. 31-63; col. 45, l. 16-33; Figure 19).

It would have been obvious to one of ordinary skill in the art to modify the apparatus of Ramsey, et al. to use both AC and DC voltage because sample stacking will occur when the

current is alternating and a more highly concentrated sample will be separated using a direct current giving a more accurate quantitative result.

Response to Arguments

Applicant's arguments filed 04/02/2003 have been fully considered but they are not persuasive.

1. Regarding the standard for anticipation, according to the MPEP, "for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." Examiner emphasis added.

The anticipation of Applicants claimed method of using three electrodes on and one floating comes from Figures 4A and 14 in US 5858187 (Ramsey, et al.) which show sheath 1 and 2 headed towards the intersection as well as that of sample (col. 2, l. 25-31; col. 3, l. 4-6) towards the waste reservoir by "... providing a method of controlling material transport in an interconnected channel structure having at least three ports, which includes actively controlling the electric potential at the at least three ports to spatially control the lateral dimensions of a sample stream" (col. 2, l. 3-8). Examiner emphasis added. In light of the foregoing, the reference anticipates both explicitly and impliedly the features and methods claimed by Applicants. The amendment fails to impart any substantial changes to the apparatus or method as claimed, therefore Examiner maintains prior 102(b) rejection.

2. Likewise, Chow, et al. teach "electrodes in communication with at least one of the channels and/or chambers formed in the interior portion of the device from the grooves or indentions in the bottom of the substrate. In the completed device, these holes function as reservoirs for facilitating fluid or material introduction into the channels or chambers of the

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interior portion of the device, as well as providing ports at which electrodes may be placed into contact with fluids within the device, allowing application of electric fields along the channels of the device to control and direct fluid transport within the device" (col. 8, l. 60 – col. 9, l. 10). Furthermore, "Controlled electrokinetic material transport and direction" as used herein, refers to electrokinetic systems as described above, which employ active control of the voltages applied at multiple, i.e., more than two, electrodes. Rephrased, such controlled electrokinetic systems concomitantly regulate voltage gradients applied across at least two intersecting channels. ... body structure which includes at least two intersecting channels or fluid conduits, e.g., interconnected, enclosed chambers, which channels include at least three unintersected termini. The intersection of two channels refers to a point at which two or more channels are in fluid communication with each other, and encompasses "T" intersections, cross intersections, 'wagon wheel' intersections of multiple channels, or any other channel geometry where two or more channels are in such fluid communication. An unintersected terminus of a channel is a point at which a channel terminates not as a result of that channel's intersection with another channel, e.g., a "T" intersection. In preferred aspects, the devices will include at least three intersecting channels having at least four unintersected termini. In a basic cross channel structure, where a single horizontal channel is intersected and crossed by a single vertical channel, controlled electrokinetic material transport operates to controllably direct material flow through the channels at the intersection. For example, assuming one was desirous of transporting a first material through the horizontal channel, e.g., from left to right, across the intersection with the vertical channel, i.e., applying a first voltage to the left terminus of this channel, and a second, lower voltage to the right terminus of this channel, or by allowing the right terminus to float (applying no voltage). However, this type of material flow through the

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intersection would result in a substantial amount of diffusion at the intersection, resulting from both the natural diffusive properties of the material being transported in the medium used, as well as convective effects at the intersection." (col. 10, l. 25-58) Again, "the systems described herein preferably utilize electrokinetic material direction and transport systems. As such, the controller systems for use in conjunction with the microfluidic devices typically include an electrical power supply and circuitry for concurrently delivering appropriate voltages to a plurality of electrodes that are placed in electrical contact with the fluids contained within the microfluidic devices." (col. 12, l. 17-24) "Still further, the power supply may apply any combination of DC, AC and pulse, depending upon the application." (col. 17, l. 61-63). Because the electrodes are used for material transport not solely heating of channels and/or chambers, it is directed to movement of material electroosmotically by AC, DC or pulsed methods as directed by computer and the power supply and does concern separation of materials and controlled flow. As stated in the previous office action, the motivation is present and taught for simultaneous control to three side channels and suggests Applicants claimed invention, therefore Examiner maintains previous 103(a) rejections.

3. Examiner points out to Applicants that copending application 09/933,993 which was not previously cited by Applicants has subject matter in common with the current Application.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of

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the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (703) 305-0435. The examiner can normally be reached on M-F 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (703) 308-3823. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

jmb
June 26, 2003


Mark L. Bell
Supervisory Patent Examiner
Technology Center 1700